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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/734,916

**Applicant(s)**

BAIK ET AL.

**Examiner**

Susan D. Coe

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 14, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 May 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-17 are currently pending.

#### ***Election/Restrictions***

2. Applicant's election without traverse of Group I, claims 1-12 and 14-17, *Raphanus* for species A, green tea for species B, and *Daucus carota* var *sativa* in the reply filed on March 24, 2005 is acknowledged.
3. Claims 6-11, 13, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 24, 2005.
4. Claims 1-5, 12, 14, 15, and 17 are examined on the merits in regards to the elected species.

#### ***Claim Objections***

5. Claim 4 is objected to because of the following informalities: in the phrase "is selected at least one selected from," "selected" is repeated twice in a manner that is not proper idiomatic English. Appropriate correction is required.
6. Claim 17 is objected to because of the following informalities: "yogurt" is misspelled in line 3. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-15, 12, 14, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating intestinal disease and constipation, does not reasonably provide enablement for preventing intestinal disease and constipation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent intestinal disease and constipation. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent intestinal disease and constipation for all potential causes of intestinal disease and constipation. The specification provides examples that show that the claimed composition functions to increase intestinal mobility, treat constipation, increase intestinal mucus, and inhibit the growth of some intestinal pathogenic bacteria. These functions would be useful in treating or even perhaps reducing the occurrence of intestinal disease. However, the specification does not

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show that the claimed composition is able prevent any disease from occurring. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of intestinal disease and constipation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 12, 14, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is indefinite because the scope of the claim is not clear. Claim 1 states that the pharmaceutical composition is one that is "essentially comprising" the claimed ingredients. "Essentially comprising" is not clear because "essentially" implies that some unrecited ingredients are excluded while "comprising" allows for the addition of any unrecited ingredients. Please see MPEP 2111.03. For the purpose of examination, the scope of the claim will be considered open to unrecited ingredients.

9. Claim 3 is indefinite because it is not clear what plants are considered "similar species" to *Camellia sinensis*.

10. Claims 5 and 15 are indefinite because the definition of "crude drug" is unclear. It is not clear what characteristics a drug must have in order to be considered a "crude drug."

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

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does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "all intestinal diseases caused by microorganism", and the claim also recites "such as *Escherichia coli* and *Salmonella typhimurium* which is the narrower statement of the range/limitation.

12. Claim 14 recites the limitation "the extract" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3-5, 12, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,299,925.

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Applicant's claims are drawn to a composition comprising radish, green tea, and carrot (*Daucus carota* var *sativa*).

US '925 teaches a composition which comprises radish, green tea, and carrot (see Example VIII and claims 1, 24, and 25). The composition is provided in a number of forms including as a powder and a tablet (see claim 36). The composition can be mixed with a beverage such as water (see column 5, lines 36-45).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925.

As stated above, the reference is considered to teach the claimed composition; however, the reference does not specifically teach formulating the composition in the forms claimed by applicant. It is well known in the art to be beneficial and routine to include pharmaceutical compositions with food products or formulate the composition as a capsule or gum. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant.

15. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925 in view of Merriam Webster's Collegiate Dictionary (10<sup>th</sup> ed. (1997) page 964).

As discussed above, the reference teaches a composition that contains radish, green tea, and carrot. The reference does not specifically teach that the radish is *Raphanus sativus*. However, as demonstrated by Webster's dictionary, *Raphanus sativus* is the Latin name for the common radish. Thus, it is reasonable to assume that the radish used in the reference is *R. sativus*. However, even if the radish used is not this specific type, a person of ordinary skill in the art would reasonably expect that this common type of radish could easily be used in the composition of US '925. The motivation for such a use would arise from the commonality of this specific radish species.



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16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

  
4-29-05

Susan D. Coe  
Primary Examiner  
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